

§ 868.5130 Anesthesia conduction filter.

(a) *Identification.* An anesthesia conduction filter is a microporous filter used while administering to a patient injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

(b) *Classification.* Class II (performance standards).

§ 868.5140 Anesthesia conduction kit.

(a) *Identification.* An anesthesia conduction kit is a device used to administer to a patient conduction, regional, or local anesthesia. The device may contain syringes, needles, and drugs.

(b) *Classification.* Class II (performance standards).

§ 868.5150 Anesthesia conduction needle.

(a) *Identification.* An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

(b) *Classification.* Class II (performance standards).

§ 868.5160 Gas machine for anesthesia or analgesia.

(a) *Gas machine for anesthesia—(1) Identification.* A gas machine for anesthesia is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency air supply.

(2) *Classification.* Class II (performance standards).

(b) *Gas machine for analgesia—(1) Identification.* A gas machine for analgesia is a device used to administer to a patient an analgesic agent, such as a nitrous oxide-oxygen mixture (maximum concentration of 70 percent nitrous oxide).

(2) *Classification.* Class II (performance standards).

§ 868.5170 Laryngotracheal topical anesthesia applicator.

(a) *Identification.* A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.

(b) *Classification.* Class II (performance standards).

§ 868.5180 Rocking bed.

(a) *Identification.* A rocking bed is a device intended for temporary use to help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

(b) *Classification.* Class II (performance standards).

§ 868.5220 Blow bottle.

(a) *Identification.* A blow bottle is a device that is intended for medical purposes to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[47 FR 31142, July 16, 1982, as amended at 54 FR 25048, June 12, 1989]

§ 868.5240 Anesthesia breathing circuit.

(a) *Identification.* An anesthesia breathing circuit is a device that is intended to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996]

§ 868.5250 Breathing circuit circulator.

(a) *Identification.* A breathing circuit circulator is a turbine device that is attached to a closed breathing circuit and that is intended to circulate anesthetic gases continuously by maintaining the unidirectional valves in an